

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE: PHARMACEUTICAL INDUSTRY)	MDL DOCKET NO. 1456
AVERAGE WHOLESALE PRICE)	
LITIGATION)	Master File No. 01-CV-12257
)	Subcategory Case No. 06-CV-11337
)	
THIS DOCUMENT RELATES TO:)	Judge Patti B. Saris
)	
<i>U.S. ex rel. Ven-A-Care of the Florida Keys,</i>)	Magistrate Judge Marianne B. Bowler
<i>Inc. v. Abbott Laboratories, Inc., et al., No.</i>)	
06-CV-11337-PBS)	
)	
<i>U.S. ex rel. Ven-A-Care of the Florida Keys,</i>)	
<i>Inc. v. Dey, Inc., et al., No. 05-CV-11084-</i>)	
PBS; and)	
)	
<i>U.S. ex rel. Ven-A-Care of the Florida Keys,</i>)	
<i>Inc. v. Boehringer Ingelheim Corp. et al.,</i>)	
No. 07-CV-10248-PBS)	
)	

**DEFENDANTS ABBOTT LABORATORIES, INC., DEY, INC., DEY, L.P, DEY L.P.,
INC., AND BOEHRINGER INGELHEIM ROXANE, INC.'S COMBINED REPLY
TO THE UNITED STATES' RESPONSE TO THE COMBINED
LOCAL RULE 56.1 STATEMENT OF ADDITIONAL MATERIAL FACTS PERTINENT
TO THE UNITED STATES' MOTIONS FOR PARTIAL
SUMMARY JUDGMENT AGAINST DEFENDANTS AND DEFENDANTS'
RESPONSE TO ADDITIONAL STATEMENT OF FACTS BY THE UNITED STATES**

PRELIMINARY STATEMENT

Defendants Abbott Laboratories Inc. (“Abbott”), Dey, Inc., Dey, L.P., and Dey L.P., Inc. (collectively, “Dey”) and Boehringer Ingelheim Roxane, Inc. (f/k/a Roxane Laboratories, Inc.) (“Roxane”) (collectively, “Defendants”) respectfully submit this reply to Defendants Combined Local Rule 56.1 Statement of Additional Material Facts Pertinent to the United States’ Motions for Partial Summary Judgment against Defendants (“Defendants’ SOAF”) (Docket No. 6447) and their response to the Additional Statement of Facts by the United States. (Dockets No. 6525 and 6527).

DEFENDANTS’ COMBINED REPLY TO THE UNITED STATES’ RESPONSE TO THE COMBINED LOCAL RULE 56.1 STATEMENT OF ADDITIONAL MATERIAL FACTS PERTINENT TO THE UNITED STATES’ MOTIONS FOR PARTIAL SUMMARY JUDGMENT AGAINST DEFENDANTS

The United States’ Response to Defendants’ SOAF does not overcome the evidence cited by Defendants, which shows the existence of genuine issues of material fact precluding the United States’ motions for partial summary judgment against Defendants. At best, the United States’ Response to Defendants’ SOAF demonstrates that there are genuine disputes of material fact precluding the United States’ motions for partial summary judgment. In many of their responses, the United States simply cites to additional evidence in the record, while failing to present evidence that controverts the testimony and document citations presented by Defendants.¹ For example, a common response is that “[t]he United States does not dispute that defendants accurately, but selectively, quoted excerpts” of a particular deposition. (*See, e.g.,*

¹ To the extent that the counter-evidence cited by the United States is relevant to its motions for partial summary judgment, it is untimely; as such evidence should have been contained in the United States’ original statements of undisputed facts. (*See* Local Rule 56.1 (“Motions for summary judgment shall include a concise statement of the material facts of record as to which the moving party contends there is no genuine issue to be tried, with page references to affidavits, depositions and other documentation. Failure to include such a statement constitutes grounds for denial of the motion.”)).

Response to SOAF 1(o)). This statement is sometimes followed with testimony of different deponents or documents that does not change the fact that the testimony cited by Defendants was given. *Id.* Another common response is that the United States does not dispute the testimony quoted, but disputes its “suggestion.” (*See, e.g.*, Response to SOAF 38(e)). Such a response is also not sufficient to overcome the evidence cited by Defendants. The United States has also failed to substantiate objections to the materiality of Defendants’ SOAF. (*See, e.g.*, Response to SOAF 18, 45(h)). In addition, throughout its Response, the United States engages in argument, explication of its legal positions, and other unresponsive commentary. (*See, e.g.*, Response to SOAF 47 (“The testimony appears to address only Ms. Duzor’s present state of mind and reflection on the nature of future reform in light of the consequences of wide-spread abuse and governments’ inability to counter its effects in a timely way”); Response to SOAF 54 (“Moreover, the Abt report’s consideration of policy issues relating to options for reforming the Medicaid drug reimbursement system is irrelevant, particularly in light of the fact that the integrity of that system has been destroyed by the conduct at issue in these cases.”)).

No further reply is required of Defendants under Local Rule 56.1, and no facts are deemed admitted or positions otherwise conceded by reason of the Defendants’ silence in reply to any particular response by the United States to Defendants’ SOAF.

**DEFENDANTS’ RESPONSES TO ADDITIONAL STATEMENTS
OF FACT BY THE UNITED STATES**

Defendants also submit their response to the Additional Statement of Facts by the United States, which were included at the end of the United States’ Response to Defendants’ SOAF. The two additional statement of facts submitted by the United States are improper and should be stricken by the Court. If these additional statements are in furtherance of the United States’ motion for partial summary judgment, they should have been submitted in connection

with the United States' 56.1 Statement in connection with that motion. To the extent that these additional statements are in opposition to Defendants' motions for partial summary judgment, they should have been submitted in response to that motion. Despite this objection, the Defendants submit the following responses. To the extent a statement of fact asserted by the United States is undisputed, it is undisputed solely for the purposes of the United States' Motions for Partial Summary Judgment against Abbott, Dey, and Roxane. Defendants reserve the right to modify or supplement their responses as necessary. Defendants reserve the right to object to the relevance of any and all facts asserted by the United States.

149.1. Representatives of pharmaceutical manufacturers have given misleading information to the government about the role of manufacturers in setting AWP's. For example, in July of 1989, a Special Committee on Aging of the United States Senate commenced hearings, Chaired by Senator David Pryor (D. Arkansas), on spiraling drug costs in the United States. *Hearings Before the Special Committee on Aging*, S. Hrg. 101-747, 101st Cong., 1st Sess. (July 18, 1989, Nov. 16, 1989), Serial No. 101-14 (Henderson Reply Ex. 87.) Eighteen pharmaceutical manufacturers were invited to present testimony, but only one attended. However, Gerald Mossinghoff, President of the Pharmaceutical Manufacturers Association, testified and submitted a written statement. During his testimony the following exchange took place:

SENATOR WARNER. In your prepared statement you mentioned that the so-called average wholesale price is, not really an accurate standard of what pharmacists actually pay for drugs. And this is what I was trying to get at. Why isn't it, and is there a better standard to use?

MR. MOSSINGHOFF. Well, the average wholesale price is not determined by our companies. It's determined in part from surveys done of our companies. It's also done by other surveys, as I think testimony today would indicate. . . (*Id.*, at 157.)

DEFENDANTS' RESPONSE: The United States' Additional Statement of Fact 149.1 is improperly included at this time and should be stricken. To the extent it is not stricken, it is disputed in its entirety. The testimony cited by the United States is not from Abbott, Dey, or Roxane. The Government has not shown that Mr. Mossinghoff was authorized to speak on

behalf of any of the defendants. Furthermore, the United States has not provided any evidence to support its contention that the testimony was “misleading.” The United States has not provided any evidence that “Eighteen pharmaceutical manufacturers were invited to present testimony, but only one attended”. It also has not included the complete testimony or written statement.

Defendants further dispute this statement as immaterial.

149.2 In October 2000, the defendants submitted a *Supplemental Analysis of Why the United States Should Decline Intervention In United States ex rel. Ven-a-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et al.* The document asserted, in part:

Third, the Relator cannot prove that AWP's are derived from information provided solely by the manufacturers. The federal and state governments decided to pay for drugs based on AWP as published by the commercial pricing services. This spring, First Data, the publisher of the Blue Book used by most state Medicaid programs, issued a Price Alert describing how it determines AWP by conducting surveys of drug wholesalers. In that Price Alert, First Data directly contradicted the theory of the Relator's Complaint:

Many customers are under the impression that the manufacturer sets the AWP. This is not true.

(Emphasis added.) This year, the commercial pricing services have undertaken to revise their published prices in response to a request from state Medicaid programs. One state Attorney General described this revision as “First Data more effectively performing the task it is already required to perform.” The services could always have revised their published prices in the same manner as they have this year, if HHS or the state Medicaid agencies had asked. (Henderson Reply Ex. 88.)

DEFENDANTS' RESPONSE: The United States' Additional Statement of Fact 149.2 is improperly included at this time and should be stricken. To the extent it is not stricken, it is disputed. The statement is supported by a reference to a cover page, page 1, and page 7 of a document. The full document is the best evidence of its contents. Defendants note that the sentence to which the United States has added emphasis is a quotation from a First DataBank Price Alert document and is not a statement authored by any defendant. The statement is further disputed because defendant Roxane is not listed on the cover page document, and the United

States has not submitted any signature page or other evidence of the document's authorship.

Defendants further dispute this statement as immaterial.

Dated: October 5, 2009

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by causing to be sent, on October 5, 2009, a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Sarah L. Reid

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